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03-31-02

PTO/SB/21 (05-03)

Approved for use through 04/30/2003. OMB 0651-0031

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TDANGAITTAI			Application Number 10/747,974			74	
TRANSMITTAL FORM			Filing Date		Decembe	December 30, 2003	
			First N	lamed Inventor	George N	A. Levinson et al.	
(to be used for all correspondence after initial filing)			Art Un	it	(TBA)	\	
			Exami	ner Name	(TBA)	· · · · · · · · · · · · · · · · · · ·	
Total Number of Pages in This Submission			Attorn	ey Docket Number	06335.00	0007	
		ENCL	SURES	(check all that apply)			
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After Final		Petition			Proprie	etary Information	
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Extension of Time	Power of Attorney, Revocation Change of Correspondence Address				Enclosure(s) a identify below):		
Express Abandonment Request			Terminal Disclaimer			O/SB/08A form, 21 references, p MI #EL941344610US	
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Firm or Individual name	Banner & Witcoff, I Robert H. Resis (R		68)	_			
Signature	Mil	15		1/2.			
Date	March 30, 2004	101	•	<u>Y</u>			
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This collection of information is required by 37 CFR 1.5. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to 12 minutes to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

PTO/SB/21 (05-03)

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TRANSMITTAL

Application Number 10/747,974

Filing Date December 30, 2003

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TRANSMITTAL			Filing Date	Decemb	December 30, 2003	
F	FORM		First Named Inventor	George	M. Levinson et al.	
(to be used for all co	rrespondence after ii	nitial filing)	Art Unit	(TBA)		
			Examiner Name	(TBA)		
Total Number of Page	s in This Submission	)	Attorney Docket Number	06335.0	0007	
		ENCLO	OSURES (check all that apply)			
Fee Transmittal F	Form		ment Papers Application)	After Group	Allowance Communication to	
Fee Attached	I	☐ Drawin	g(s)		al Communication to Board of als and Interferences	
Preliminary Amer	ndment	Licensi	ng-related Papers		al Communication to Group al Notice, Brief, Reply Brief)	
After Final		Petition	1	Propri	ietary Information	
Affidavits/dec	laration(s)		n to Convert to a onal Application	☐ Status	s Letter	
Extension of Time	e Request		of Attorney, Revocation e of Correspondence Address		r Enclosure(s) e identify below):	
Express Abandonment Request		☐ Terminal Disclaimer ☐ Request for Refund		E	FO/SB/08A form, 21 references, op MI #EL941344610US	
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Document(s)		Rema			_	
Response to Miss Incomplete Applic		Please charge any additional fees or credit overpayment to Deposit Account No. 19-0733. A duplicate copy of this sheet is enclosed.				
Response to Parts under 3 1.52 or 1.53						
	SIGNA	TURE OF A	APPLICANT, ATTORNEY, C	R AGENT		
Firm or	Banner & Witcoff, I					
Individual name	Robert H. Resis (R	eg. No. 32,1	68)			
Signature	Mol	12	1/2			
Date	March 30, 2004					
		CE	RTIFICATE OF MAILING			
I hereby certify that the Service with sufficient Alexandria, VA 22313	nt postage as first o	dass mail in	imile transmitted to the USPTO an envelope addressed to: C	or deposite ommissione	d with the United States Postal r for Patents, P.O. Box 1450,	
Typed or printed name	е					
Signature				Date		

This collection of information is required by 37 CFR 1.5. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to 12 minutes to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

MAR 3 0 2004 W

#### **PATENT**

## IN THE UNITED STATES PATENT AND TRADEMARK OFFICE (Case No. 06335.00007)

In the Application of:	)
George M. Levinson et al.	)
Serial No.: 10/747,974	) Group Art Unit: (TBA)
Filed: December 30, 2003	) Examiner: (TBA)
For: System, Method, and Computer-Readable	)
Medium for Collection of Environmental Data and	)
Generation of User Report for Compliance with FDA	)
Requirements	)

### **INFORMATION DISCLOSURE STATEMENT**

Commissioner for Patents P.O. Box 1450 Alexandria, VA 22313-1450

Sir:

Pursuant to 37 C.F.R. §§1.97 and 1.98, applicants wish to make the following references of record in the above-identified application. These references were cited in a Petition to Make Special filed on January 28, 2004. These references may be material to the patentability of the presently pending claims. A copy of the reference cited below are enclosed along with a completed PTO/SB/08A form.

#### U.S. Patents

	Patent No.	<u>Inventor</u>	<u>Issue Date</u>	
1.	4,298,955	Munday et al.	11-03-81	
2.	5,103,391	Barrett	04-07-92	
3.	5,631,839	Lemoine	05-20-97	

#### U.S. Patents

Patent No.	<u>Inventor</u>	Issue Date
5,691,895	Kurtzberg et al.	11-25-97
5,719,796	Chen	02-17-98
5,787,021	Samaha	07-28-98
5,798,945	Benda .	08-25-98
5,838,906	Doyle et al.	11-17-98
5,862,054	Li	01-19-99
5,892,690	Boatman et al.	04-06-99
6,163,732	Petke et al.	12-19-00
6,437,692	Petite et al	08-20-02
6,523,045	Beatty	02-18-03
6,539,271	Lech et al.	03-25-03
6,574,522	Douglas	06-03-03
6,604,023	Brown et al.	08-05-03
	5,691,895 5,719,796 5,787,021 5,798,945 5,838,906 5,862,054 5,892,690 6,163,732 6,437,692 6,523,045 6,539,271 6,574,522	5,691,895  Kurtzberg et al.  5,719,796  Chen  5,787,021  Samaha  5,798,945  Benda  5,838,906  Doyle et al.  5,862,054  Li  5,892,690  Boatman et al.  6,163,732  Petke et al.  6,437,692  Petite et al  6,523,045  Beatty  6,539,271  Lech et al.  6,574,522  Douglas

#### Other Prior Art - Non-Patent Literature Documents

- 17. Compliance Software Solutions Corp. web page description of its Environmental Monitoring Software System (EMSS) (3 sheets);
- 18. BD Diagnostic Systems, Industrial web page description of the Environmental Monitoring Software System (EMSS) of Compliance Software Solutions Corp. (2 sheets);
- 19. BD Diagnostic Systems, Industrial web page description of the Environmental Monitoring Software System (EMSS) of Compliance Software Solutions Corp. (3 sheets);
- 20. Compliance Software Solutions Corp. web page description of its Environmental Monitoring Software System (EMSS), in connection with 21 CFR Part 11 Compliance Assessment (4 sheets);

Banner & Witcoff, Ltd. Ten S. Wacker Drive, Suite 3000 Chicago, Illinois 60606 Telephone: 312/463-5000 21. Compliance Software Solutions Corp. web page description of its Environmental

Monitoring Software System (EMSS) (168 sheets).

The present Disclosure Statement is being submitted in compliance with 37 C.F.R. 1.56

as an Examiner might consider the cited documents important in deciding whether to allow the

application to issue as a patent, but the citation of such documents is not to be construed as an

admission that such documents are necessarily relevant or prior art. No representation is

intended that the cited documents represent the results of a complete search, and it is anticipated

that the Examiner in the normal course of examination, will make an independent search and will

determine the best prior art and in the course of such search, will review for relevance the

documents cited on the attached form even if not initialed.

The accompanying Information Disclosure Statement is being filed within three months

of the U.S. filing date or before the mailing date of a first Office Action on the merits. No

By:

certification or fee is required.

Early and favorable consideration is earnestly solicited.

Respectfully submitted,

BANNER & WITCOFF, LTD.

Dated: March 30, 2004

Robert H. Resis

Reg. No. 32,168

Banner & Witcoff, Ltd. Ten S. Wacker Drive, Suite 3000 Chicago, Illinois 60606 Telephone: 312/463-5000

# INFORMATION DISCLOSURE STATEMENT BY APPLICANT (use as many sheets as necessary) Sheet 1 of 2

Complete if Known					
Application Number	10/747,974				
Filing Date	December 30, 2003				
First Named Inventor	Levinson et al.				
Art Unit	(TBA)				
Examiner Name	(TBA)				
Attorney Docket Number	06335.00007				

		Document Number	Publication D		Name of	Patentee or Applicant of	Pages, Columns, Lines, Where	Oalaraa
Examiner Initials *	Cite No. <sup>1</sup>	Number - Kind Code <sup>2</sup> (if known)	MM-DD-YY			Cited Document	Passages or Relevant Figures Appear	
		4,298,955	11-03-81		Munday	et al.		
		5,103,391	04-07-92		Barrett			
		5,631,839	05-20-97		Lemoine	)		
		5,691,895	11-25-97		Kurtzbei	g et al.		
		5,719,796	02-17-98		Chen			
		5,787,021	07-28-98		Samaha			
		5,798,945	08-25-98		Benda			
		5,838,906	11-17-98		Doyle et	al.		
		5,862,054	01-19-99		Li			
		5,892,690	04-06-99		Boatma	n et al.		
		6,163,732	12-19-00		Petke et	al.		
		6,437,692	08-20-02		Petite et	al		
		6,523,045	02-18-03		Beatty			
		6,539,271	03-25-03	-	Lech et	al.		
- ,		6,574,522	06-03-03		Douglas			
		6,604,023	08-05-03		Brown e	t al		
			FOREIG	N PA	TENT D	OCUMENTS		
Examiner Initials*	Cite No.1	Foreign Patent Doc  Country Code <sup>3</sup> - Number <sup>4</sup> - Kind		l	blication Date	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant	T⁵
Examiner Initials*	Cite No. <sup>1</sup>		ument	Pul	blication	Name of Patentee or Applicant of Cited	Where Relevant	1
Examiner					Date	T T		

\*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant. 1 Applicant's unique citation designation number (optional). 2 See Kinds Codes of USPTO Patent Documents at www.uspto.gov or MPEP 901.04. 3 Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). 4 For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. 5 Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST. 16 if possible. 6 Applicant is to place a check mark here if English language Translation is attached.

This collection of information is required by 37 CFR 1.97 and 1.98. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 2 hours to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

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					Group Art Unit	
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	Sheet	2	of	2	Attorney Docket Number	

	OTHER PRIOR ART NON PATENT LITERATURE DOCUMENTS					
Examiner Initials *	Cite No.1	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T 2			
		Compliance Software Solutions Corp. web page description of its Environmental Monitoring Software System (EMSS) (3 sheets);				
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		Compliance Software Solutions Corp. web page description of its Environmental Monitoring Software System (EMSS) (168 sheets).				
<u> </u>						

Examiner	Date	
Signature	Considered	 

<sup>\*</sup>EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

<sup>1</sup> Applicant's unique citation designation number (optional). 2 Applicant is to place a check mark here if English language Translation is attached. This collection of information is required by 37 CFR 1.98. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 120 minutes to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.



## CERTIFICATE OF MAILING (PATENT)

Express Mail No. EL941344610US

Deposited March 30, 2004

I hereby certify that the attached correspondence, identified below, is being deposited with the United States Postal Service as "Express Mail Post Office to Addressee" under 37 CFR 1.10 on the date indicated above and is addressed to the Attn: Commissioner for Patent, P.O. Box 1450, Alexandria, VA 22313-1450.

Ву:

Application of: George M. Levinson

Title: System, Method, and Computer-Readable Medium for Collection of Environmental Data

and Generation of User Report for Compliance with FDA Requirements

Serial No. 10/747,974

X Transmittal sheet (in duplicate)

X Information Disclosure Statement

X 21 references

X PTO/SB/08A form

X Return Receipt Postcard

Attorney Docket No. 06335.00007

BANNER & WITCOFF, LTD.

Ten South Wacker Drive Chicago, Illinois 60606 (312) 463-5000